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(54) **Aspiration needle**

(57) Aspiration needles for bone-marrow aspiration comprising a hollow needle 20 with perforations 38 at the distal end enable a larger and more representative sample of bone-marrow aspirate to be obtained thus reducing the sampling error inherent in methods using a needle with a single opening at the end. The needle includes a transverse-bar, finger-grip handle 24 for ease in passing the needle into bone, especially the compact bone of the ilium, in order to avoid sternal puncture, and to reduce sampling error further by sampling this thick marrow-containing region. The needle forms part of an assembly comprising a stylet removably located within the hollow needle, and a palm handle 26.

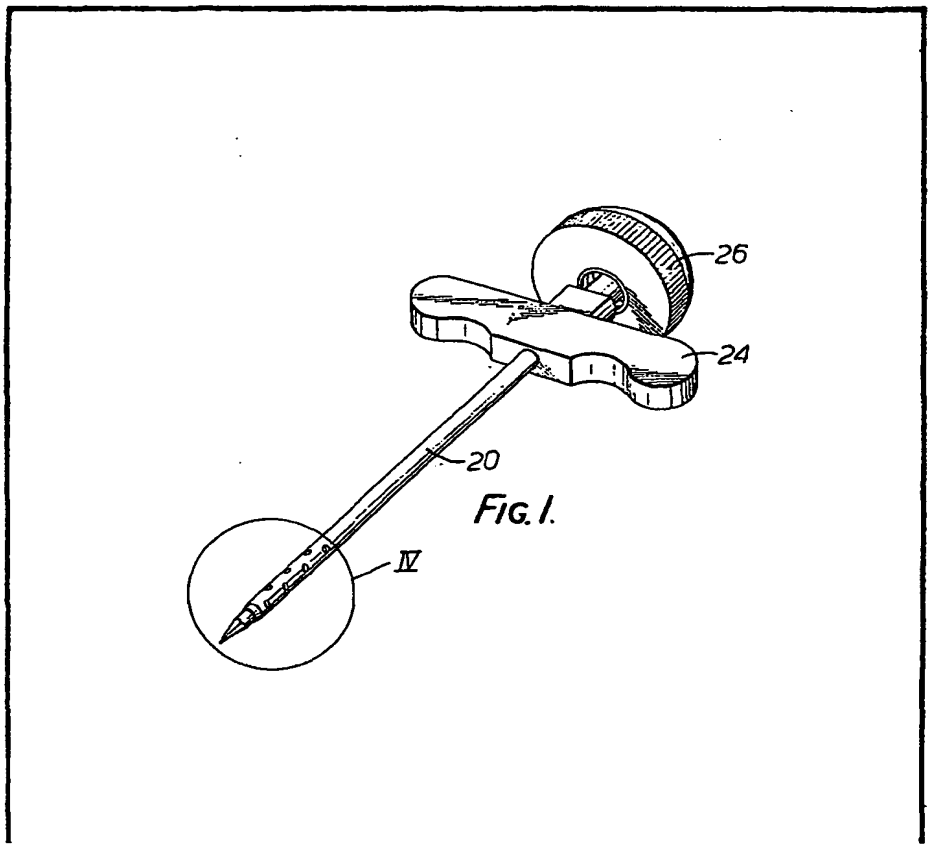

FIG. 1.

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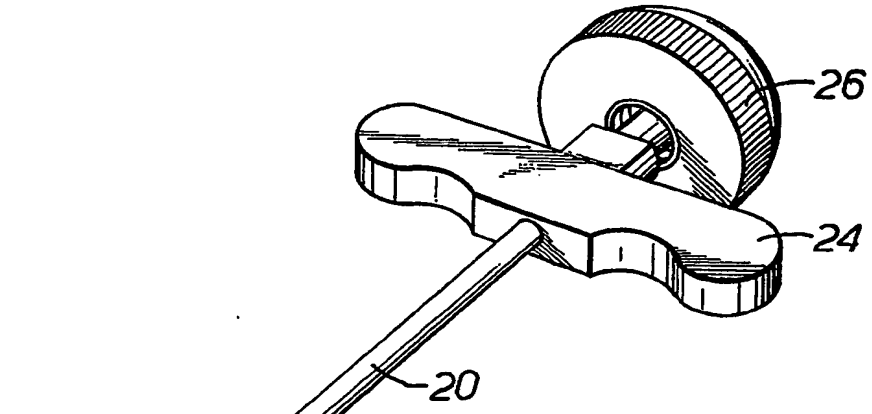


FIG. 1.

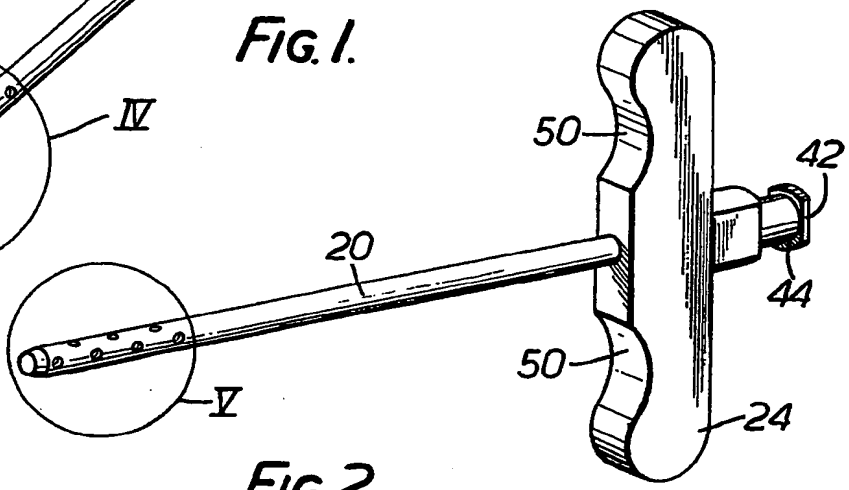


FIG. 2.

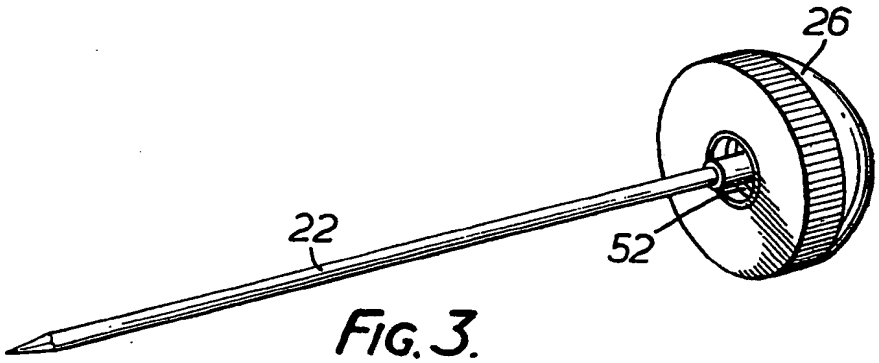
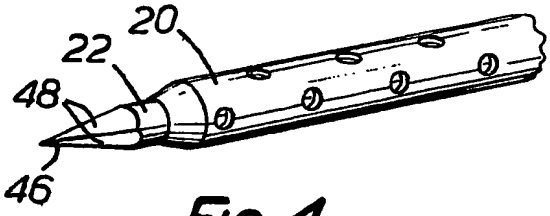


FIG. 3.



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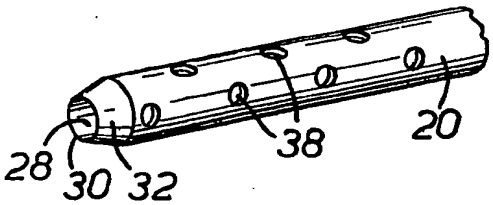

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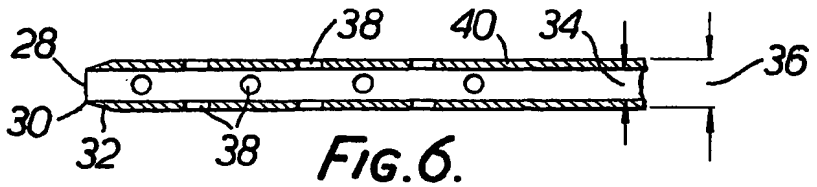

FIG. 6.

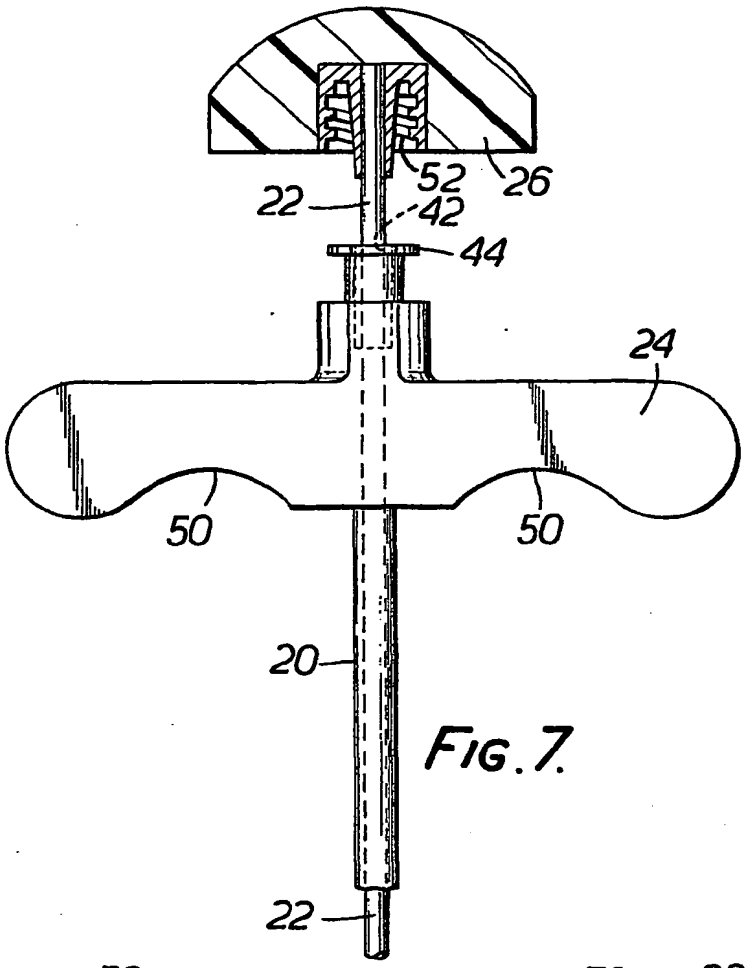

FIG. 7.

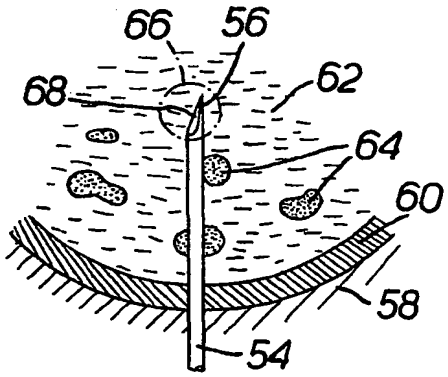

FIG. 8.

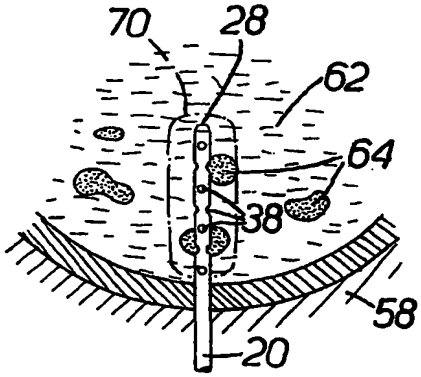

FIG. 9.

SPECIFICATION

Aspiration needle

The present invention relates to an aspiration or drainage needle and an aspiration or drainage needle assembly, particularly for use in bone marrow aspiration and harvesting, and also to an aspiration method.

The value of bone-marrow aspiration in the investigation and diagnosis of haematological as well as non-haematological malignancies (for example, leukaemia) is well established. Bone-marrow aspiration is commonly effected at the sternum, although it can also be effected at the ilium (anterior or posterior iliac crest) and at the spinous processes of lumbar vertebrae. In carrying out the aspiration procedure, the aspiration needle has to be passed first through the skin and soft tissue and, secondly, through the bony cortex, before reaching the spongy bone containing bone marrow, and then it has to be passed into the spongy bone to an adequate depth before aspiration of the bone marrow is attempted.

Various needle assemblies are used for aspirating bone marrow. Examples of bone biopsy needle assemblies commonly used for aspiration are those known as the "Salah Biopsy Needle" and the "Klima Biopsy Needle", which were first introduced in the 1930's and have changed little since. Another example of a bone-marrow aspiration needle assembly is that described in United States Patent 4 356 828 (Jamshidi). Such needle assemblies generally comprise an elongate hollow needle having open distal and proximal ends with a cutting edge at the distal end, an elongate stylet or trocar needle having a closed distal end, and means to position the stylet releasably within the needle, the arrangement being such that the needle and stylet can be inserted into tissue as a unit. In using such needle assemblies for bone-marrow aspiration, the needle/stylet assembly is carefully advanced, under local anaesthetic, through the soft tissue and then through the bony cortex. The stylet assists in penetrating the bony cortex. When the assembly enters the spongy bone containing marrow (indicated by decreased resistance to the advance of the assembly), the assembly is advanced to the required depth and then the stylet is withdrawn. Suction is applied, for example by means of a syringe, at the proximal end of the needle in order to aspirate the marrow. When sufficient aspirate has been obtained, the stylet is replaced in the hollow needle and the needle/stylet assembly is withdrawn.

It has been found that, in practice, a number of difficulties occur with the use of such needle assemblies. One important difficulty concerns the sampling error inherent in the conventional aspiration procedure. The sample of aspirate is taken only through the open distal end of the hollow needle, but the constitution of the bone marrow is often non-uniform, bone marrow seldom being involved uniformly in pathological various haematological and non-haematological malignancies being well known from aspiration and biopsy specimens. The constituents of the sample of aspirate will therefore depend largely on the position of lodgement of the open distal end of the needle within the marrow cavity. If the marrow contains discrete regions of pathological lesion and the aspiration needle either misses or passes right through those regions, it is quite possible for the sample of aspirate to show normal marrow and to give no indication of the presence of the regions of pathological lesion, and that can lead to an incorrect diagnosis with possibly fatal results. A full biopsy sample, generally known as a "long-core biopsy", in which a complete "core" of the marrow is extracted for examination (using, for example, the biopsy needle described and claimed in our British Patent Application No. 81.17836 (Publication No. GB 2 099 703A; also U.S. Patent Application S.N. 348 757)) may well show the presence of pathological lesions. The taking of a long-core biopsy is, however, a more severe procedure and should normally be carried out only infrequently, whereas the taking of marrow samples by aspiration can be carried out more frequently.

Further difficulties arise particularly with aspiration procedures carried out at the sternum. The usual site for sternal puncture, namely the upper part of the sternal body at the level of the second intercostal space, contains only small amounts of marrow tissue with only a shallow depth of marrow, and thus it is not possible to obtain large amounts of aspirate from this site. A second difficulty is that the patient can see the whole procedure and is often understandably apprehensive as the needle is introduced into his chest just above the heart. Moreover, a number of deaths resulting from such sternal puncture have been reported, caused by the needle being passed right through the shallow sternum bone and piercing the heart or pericardium.

Despite those difficulties, aspiration is still commonly carried out by sternal puncture, partly because many of the commonly available aspiration needles were designed primarily for use at the sternal site and either are not suitable for use at other sites or can be used at other sites only with difficulty. The needles tend to be too short for satisfactory use at the ilium and are often not strong enough to penetrate the very compact bone in this region without risk of the needle bending. Also, when aspiration is attempted at the anterior superior iliac spinous area using such needles, the needle tends to slip off the iliac crest.

The present invention provides an aspiration needle comprising

an elongate hollow needle having a proximal end, a distal end, a longitudinal axis and a substantially cylindrical side wall, and

a handle provided at or toward the said proximal end and being substantially in the

a plurality of perforations provided in the said side wall at or in the region of the said distal end.

The present invention also provides an aspiration needle assembly having a proximal end, a distal end and a longitudinal axis, and comprising

an elongate hollow needle having an open proximal end and a substantially cylindrical side wall with a plurality of perforations provided in the said side wall at or in the region of the said distal end,

an elongate stylet capable of being received within the said hollow needle through its open proximal end,

a first handle provided at or toward the proximal end of the assembly and being substantially in the form of a transverse bar, and

a second handle provided at the proximal end of the assembly and being shaped for reception in the palm of a hand,

the assembly being capable of being inserted into tissue as a unit, and being such that the stylet can be withdrawn from the hollow needle while the latter remains inserted into the tissue to enable aspiration to be effected.

Preferably, the assembly is also such that the stylet can subsequently be re-inserted into the hollow needle prior to withdrawal of the latter from the tissue.

The aspiration needle and aspiration needle assembly according to the present invention enable a number of problems associated with conventional bone-marrow aspiration needles and techniques as discussed above to be overcome. In particular, the provision of a plurality of perforations in the side wall of the hollow needle forming part of the aspiration needle and aspiration needle assembly according to the invention enables samples of aspirate to be taken from much larger regions of the bone marrow thus substantially reducing the risk of missing pathological lesions when carrying out aspiration, with a consequent substantial reduction in the sampling error inherent in the use of conventional aspiration needles. This in turn can result in a reduction in the number of aspirations having to be carried out on the patient in order to ensure a correct diagnosis.

Although there has long been recognition that aspiration of bone marrow from a single, very local, site immediately surrounding the tip of an aspiration needle is inadequate and it has long been appreciated that, in order to achieve adequate sampling, it is advisable to sample several local sites within a single bone-marrow cavity as well as sampling several different cavities (see, for example, H. R. Bierman and K. H. Kelly, Multiple marrow aspiration in man from the posterior ilium, *Blood*, 1956, *11*, 370—374; A. H. Ragab and W. M. Crist, Morphologic discordance in acute leukemia, *The New England Journal of Medicine*, 1972, *287*, 1134—1135; A. Islam, D. Value of long-core biopsy in detection of discrete bone-marrow lesions, *The Lancet*, 1979, *i*, 878), this has previously been achieved by carrying out several aspirations within the same cavity with relocation of the needle after each aspiration, for example, by rotation of the needle (in the case of a needle with an angled tip) and by further insertion or reinsertion of the needle (see, for example, Bierman and Kelly, *loc. cit.*). There has not previously been any suggestion of the present solution to the problem by providing a needle with a plurality of side holes to enable simultaneous aspiration of multiple local sites in order to obtain a representative sample.

The hollow needle forming part of the aspiration needle and aspiration needle assembly according to the invention may suitably contain from 7 to 20, preferably from 7 to 15, and especially from 10 to 15, perforations in the side wall of the needle. The number of perforations should, of course, be sufficient to give the desired representative sampling from multiple sites, but should not, on the other hand, be so great that too large an amount of aspirate is obtained too quickly. Because, in use, aspirate will be drawn from a small local region around each perforation, the perforations need not be spaced very closely together. Adjacent perforations may, for example, be from 2 to 10 mm apart, with perforation diameters of, for example, from 0.5 to 2 mm. In choosing the number, size and spacing of the perforations it is, of course, necessary to ensure that the strength of the needle is not reduced too greatly by the presence of the perforations. The choice of number, size and spacing of the perforations will also be affected by the intended use of the needle, for example whether it is intended for use at a particular site, such as the sternum or the ilium, and whether it is intended for use in children or adults. Also, needles intended for use in harvesting bone marrow may be designed to take a larger sample of aspirate than are needles intended for taking aspirate samples for diagnostic testing.

The thickest and largest marrow-containing area in both children and adults is the posterior iliac spinous area and the aspiration needle and aspiration needle assembly according to the invention are advantageously used in that area in order to facilitate the obtention of an adequate and representative sample of aspirate. Another advantage of effecting aspiration in this region is that it is easily accessible and is distant from any important organs, thus reducing the risk of accidental puncture of organs and other structures and of other complications. Furthermore, because the region is not visible to the patient, the degree of anxiety by the patient, as associated particularly with sternal puncture, is reduced.

The aspiration needle or aspiration needle assembly according to the invention includes, at or in the region of its proximal end, a handle in the form of a transverse bar, preferably extending

longitudinal axis. This first handle serves as a finger-grip handle and, especially in conjunction with the second handle forming part of the aspiration needle assembly according to the invention, enables the surgeon to achieve a good, firm and steady grip on the instrument. The second handle is shaped for reception in the palm of the hand and the arrangement of the two handles enables the assembly to be held with the second handle in the palm of the surgeon's hand and with the first handle being gripped by one or more fingers of the same hand. This enables the surgeon to apply firm, even and steady pressure to the assembly while inserting it into the patient, optionally with a regular clockwise-anticlockwise rotatory movement of the needle, and renders the assembly particularly suitable for insertion into the compact bone of the ilium.

The first, finger-grip handle advantageously contains one or more finger-receiving recesses in a side of the transverse bar facing toward the distal end of the needle, preferably with at least one finger-receiving recess in the transverse bar on each side of the longitudinal axis of the needle. The second, palm handle is advantageously substantially dome-shaped, and preferably is substantially hemispherical.

The elongate hollow needle forming part of the aspiration needle and aspiration needle assembly according to the invention will normally have an open proximal end. In the aspiration needle assembly, an elongate stylet can be received within the hollow needle through the open proximal end. Preferably, the distal end of the hollow needle is also open, in which case the stylet may have a pointed distal end which projects through the open distal end of the hollow needle when the stylet is fully received within the hollow needle. The pointed stylet may then serve as a trocar.

The hollow needle is preferably provided, at or in the region of its proximal end, with means for attachment of a device for the application of a reduced pressure (sometimes referred to as negative pressure), for example a syringe. Such means may suitably be provided at the open proximal end of the hollow needle, so that the said device may be attached thereto when the stylet has been withdrawn. The proximal ends of the hollow needle and stylet may be provided with respective mutual engagement means to secure the stylet within the hollow needle, and advantageously the means for attachment of the reduced-pressure-application device constitutes the part of the said mutual engagement means provided on the hollow needle. The part of the said mutual engagement means provided on the stylet may be provided on the second handle at the proximal end of the stylet.

One form of aspiration needle assembly according to the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of the aspiration needle assembly;

Fig. 2 is a perspective view of the hollow needle forming part of the aspiration needle assembly shown in Fig. 1;

Fig. 3 is a perspective view of the stylet forming part of the aspiration needle assembly shown in Fig. 1;

Fig. 4 is an enlarged view of the portion IV indicated in Fig. 1;

Fig. 5 is an enlarged view of the portion V indicated in Fig. 2;

Fig. 6 is a longitudinal cross-section through the portion V shown in Fig. 5;

Fig. 7 is an enlarged side view, partly in cross-section, of the proximal end and handles of the aspiration needle assembly shown in Fig. 1, with the stylet partly withdrawn from the hollow needle;

Fig. 8 is a schematic, partly cross-sectional, view of a conventional bone-marrow aspiration needle *in situ* in a bone; and

Fig. 9 is a schematic, partly cross-sectional, view of the aspiration needle shown in Fig. 2 *in situ* in a bone.

The aspiration needle assembly (Fig. 1) comprises (i) an elongate hollow needle 20 (Fig. 2), (ii) an elongate stylet 22 (Fig. 3), (iii) a first handle 24 (Fig. 2), and (iv) a second handle 26 (Fig. 3).

The elongate hollow needle 20 (Figs. 2 and 5) has an open distal end 28 provided with a cutting edge 30 and an external bevel 32, although it may alternatively or additionally be provided with a plurality of shallow external flutes (for example, as in the bone marrow biopsy needle illustrated in our British Patent Application No. 81.17836 mentioned above). The hollow needle has a smooth external surface with a uniform external circular cross-section 34 (Fig. 6) between the distal end 28 (excluding the bevel 32 and/or any fluting) and the first handle 24, and its external diameter may suitably be from 1 to 5 mm, advantageously from 2 to 5 mm, and preferably from 2 to 4 mm; its overall length, between the distal end 28 and the first handle 24, may be from 60 to 120 mm, advantageously from 70 to 120 mm, and preferably from 70 to 90 mm. The hollow needle is also of uniform internal circular cross-section 36 (Fig. 6) throughout the major portion of its length, that is to say at least between the distal end 28 and the first handle 24, suitably with an internal diameter of from 0.75 to 4 mm, advantageously from 1.5 to 4 mm, and preferably from 1.5 to 3 mm.

Towards its distal end 28, the hollow needle 20 is provided with a plurality of perforations 38 in its cylindrical side wall 40 (Figs. 5 and 6). The number of perforations 38 may suitably be from 7 to 20, advantageously from 7 to 15, preferably from 10 to 15, and each perforation 38 may suitably be of from 0.5 to 2 mm diameter, preferably of from 0.75 to 1.5 mm diameter. Adjacent perforations 38 in the same row (parallel to the longitudinal axis) may suitably be from 2 to 10 mm apart, preferably from 2.5 to 7.5 mm

plane at right angles to that containing a first row of perforations 38 may be positioned midway between the perforations 38 in the first row. The hollow needle 20 may suitably contain four such rows of perforations 38. The perforations 38 should not normally extend along the hollow needle 20 for more than about 30 mm, preferably not more than 25 mm, and especially not more than 20 mm, from the distal end 28, because it is important that the entire distal portion of the hollow needle 20 that contains perforations 38 should be able, in use, to be accommodated within the marrow cavity of the bone.

The proximal end 42 (Figs. 2 and 7) of the hollow needle 20 is open and is provided with a flange 44, suitably constituting the male part of a standard "Luer-Lok" syringe fitting, for attachment of a syringe or other device for the application of a reduced pressure in order to withdraw a sample of aspirate from the bone marrow.

The elongate stylet 22 (Fig. 3) is capable of being received within the hollow needle 20 to fit snugly therein when fully inserted into the hollow needle 20 through its open proximal end 42 (Fig. 1). Accordingly, it is of uniform external circular cross-section throughout the major portion of its length, preferably with an external diameter about 0.1 mm less than the internal diameter of the hollow needle 20. The stylet 22 has a pointed pyramidal distal end 46 (and thus it constitutes a trocar), suitably with three or four facets 48, preferably three facets, each extending about 2 to 4 mm along the stylet, with sharp cutting edges where adjoining facets 48 meet. The pointed distal end 46 of the stylet 22 projects through the open distal end 28 of the hollow needle 20 (Figs. 1 and 4) when the stylet 22 is fully received within the hollow needle 20.

The first handle 24 (Figs. 2 and 7) is attached to the hollow needle 20 toward its proximal end 42 and is in the form of a transverse bar extending across and substantially at right angles to the longitudinal axis of the hollow needle 20. It is provided, in the side of the bar facing toward the distal end of the needle assembly, with two finger-receiving recesses 50, one in each half of the bar on each side, respectively, of the longitudinal axis of the hollow needle.

The second handle 26 (Figs. 3 and 7) is attached to the stylet at its proximal end and is substantially dome-shaped and, more particularly, substantially hemispherical, so as to be receivable in the palm of the operator's hand. Within the base of the second handle 26 is a female screw-thread 52 for engagement with the syringe-engaging flange 44, in order to secure the stylet 22 within the hollow needle 20 when fully inserted therein (Figs. 1 and 7). The arrangement is such that, when the stylet 22 is secured within the hollow needle 20, the operator can use and manipulate the needle assembly by holding it with the second, palm handle 26 in the palm of his hand extended around the first, finger-grip handle 24.

The aspiration needle assembly may be entirely of stainless steel but parts of the assembly that are not, in use, actually inserted into the patient may alternatively be of other materials. For example, the proximal end 42 of the hollow needle with the flange 44, the female screw-thread 52, and the handles 24, and 26 may be of chrome-plated brass, aluminium, or a plastics material.

With the needle assembly assembled in the manner shown in Fig. 1, and with local anaesthetic having been applied to the patient's skin, subcutaneous tissue and periosteum, the pointed tip 46 of the stylet 22 may be inserted into the patient (without any initial skin incision being necessary) and the assembly may be gradually advanced through the soft tissue and then through the bony cortex, by rotating the assembly in a clockwise-anticlockwise manner and pushing on the dome-shaped, second handle 26, while holding the handles in the manner described above. It has been found that the arrangement of the pointed pyramidal distal end 46 of the stylet 22 and the bevelled distal end 32 of the hollow needle 20 with the cutting edge 30 described above enables the assembly to cut through the soft tissue and the bony cortex in a particularly easy and clean manner. Moreover, the arrangement of the two handles 24, 26 described above enables a significant amount of manual pressure to be applied to the end of the needle assembly, both in rotating the needle assembly in a clockwise-anticlockwise manner in order to cut the tissue and in actually advancing the needle through the tissue, thus rendering it relatively easy to pass the needle assembly through the soft tissue and bony cortex.

When the spongy bone has been reached (indicated by decreased resistance to the advance of the assembly), the advance of the assembly is continued until it has reached an adequate depth within the marrow cavity. Here it is important to ensure that the assembly has been inserted to a sufficient depth to ensure that all the perforations 38 in the hollow needle 20 are contained within the marrow cavity (see Fig. 9) if the presence of air bubbles and extraneous soft tissue in the aspirate is to be avoided. The stylet 22 is then rotated to unlock the female screw-thread 52 from the flange 44 and it is withdrawn from the hollow needle 20. A syringe is then attached to the proximal end 42 of the hollow needle 20, by means of the syringe-engaging flange 44, and suction is applied by means of the syringe in order to withdraw the desired amount of aspirate sample into the syringe.

It is here that the presence of the perforations 38 in the cylindrical side wall 40 of the hollow needle 20 is important. As shown schematically in Fig. 8, a conventional hollow bone-marrow aspiration needle 54, with an angled, pointed, distal end 56, which has been passed through

spongy bone of a marrow cavity comprising both normal marrow 62 and pathological lesions, 64, can pass right through pathological lesions 64 with the needle tip 56 coming to rest in a region of normal marrow 62. When suction is applied to the proximal end (not shown) of the needle 54, the aspirate sample will be drawn only from the region 66 immediately surrounding the angled opening 68 in the distal end 56 of the needle 54, and thus the aspirate sample in the syringe will show only normal marrow 62.

In contrast thereto, when using an aspiration needle according to the invention in an identical position within the marrow cavity (Fig. 9), the aspirate sample will be drawn into the hollow needle 20 through the perforations 38 as well as through the open distal end 28 of the needle 20. The sample of aspirate drawn into the syringe will thus be drawn from the whole of the region 70 and will therefore show cells from the pathological lesions 64 as well as from the normal marrow 62, even though the distal end 28 of the needle 20 is located in a region of normal marrow 62. The aspiration needle and aspiration needle assembly according to the invention thus provide an elegant solution to the long-appreciated problem of achieving adequate and representative sampling of the marrow in the well-known diagnostic procedure of bone-marrow aspiration.

When the desired sample of aspirate has been withdrawn into the syringe, the syringe is detached from the proximal end 42 of the hollow needle 20 and the aspirate sample is sent for analysis. The stylet 22 is then fully replaced within the hollow needle 20 so as to close the distal end 28 and the perforations 38 of the hollow needle 20, and it is locked into position by rotating it so that the female screw-thread 52 again engages the flange 44. The entire needle assembly is then carefully withdrawn from the patient.

The aspiration needle assembly described above and shown in the accompanying drawings is particularly suited for use at the ilium, especially the posterior iliac crest, but aspiration needles and aspiration needle assemblies according to the invention may also be used at other sites having adequate thickness of marrow, it merely being necessary to ensure that the length of the distal portion of the hollow needle which contains perforations can be fully accommodated within the marrow cavity if the presence of extraneous matter in the aspirate sample is to be avoided.

Aspiration needles and aspiration needle assemblies according to the invention may be used on both human and animal patients, who may be living or dead. For example, they may be used in diagnosis on living patients and in post-mortem examinations, as well as being used in carrying out experiments on cadavers and on living or dead animals. They may also be used, for example, in harvesting bone marrow for various

Claims

1. An aspiration needle comprising
an elongate hollow needle having a proximal end, a distal end, a longitudinal axis and a substantially cylindrical side wall, and
a handle provided at or toward the said proximal end and being substantially in the form of a transverse bar, with
a plurality of perforations provided in the said side wall at or in the region of the said distal end.

2. An aspiration needle as claimed in claim 1, wherein the said distal end is open.

3. An aspiration needle as claimed in claim 2, wherein the said distal end is provided with a cutting edge.

4. An aspiration needle as claimed in any one of claims 1 to 3, wherein the said distal end is externally bevelled.

5. An aspiration needle as claimed in any one of claims 1 to 4, wherein the said distal end is provided with a plurality of external flutes.

6. An aspiration needle as claimed in any one of claims 1 to 5, which comprises, at or in the region of the said proximal end, means for attachment of a device for the application of a reduced pressure.

7. An aspiration needle as claimed in any one of claims 1 to 5, wherein the said proximal end is open and is provided with means for attachment of a device for the application of a reduced pressure.

8. An aspiration needle as claimed in any one of claims 1 to 5, wherein the said proximal end is open and is provided with means for attachment of a syringe.

9. An aspiration needle as claimed in any one of claims 1 to 8, wherein the number of the said perforations is from 7 to 20.

10. An aspiration needle as claimed in any one of claims 1 to 8, wherein the number of the said perforations is from 7 to 15.

11. An aspiration needle as claimed in any one of claims 1 to 8, wherein the number of the said perforations is from 10 to 15.

12. An aspiration needle as claimed in any one of claims 1 to 11, wherein the elongate hollow needle is of uniform internal circular cross-section from the said distal end to the said handle.

13. An aspiration needle as claimed in claim 12, wherein the elongate hollow needle has an internal diameter within the range of from 1.5 to 4 mm.

14. An aspiration needle as claimed in claim 12, wherein the elongate hollow needle has an internal diameter within the range of from 1.5 to 3 mm.

15. An aspiration needle as claimed in any one of claims 1 to 14, wherein the elongate hollow needle is of uniform external circular cross-section between the said distal end (excluding any bevel and/or fluting at the distal end) and the said handle.

16. An aspiration needle as claimed in claim

external diameter within the range of from 2 to 5 mm.

17. An aspiration needle as claimed in claim 15, wherein the elongate hollow needle has an external diameter within the range of from 2 to 4 mm.

18. An aspiration needle as claimed in any one of claims 1 to 17, wherein the said handle is in the form of a transverse bar extending across and substantially at right angles to the said longitudinal axis.

19. An aspiration needle as claimed in any one of claims 1 to 18, wherein the said handle contains one or more finger-receiving recesses in a side facing towards the said distal end.

20. An aspiration needle as claimed in claim 19, wherein at least one of the said finger-receiving recesses is present on each side of the said longitudinal axis.

21. An aspiration needle assembly having a proximal end, a distal end and a longitudinal axis, and comprising

an elongate hollow needle having an open proximal end and a substantially cylindrical side wall with a plurality of perforations provided in the said side wall at or in the region of the said distal end,

an elongate stylet capable of being received within the said hollow needle through its open proximal end,

a first handle provided at or toward the proximal end of the assembly and being substantially in the form of a transverse bar, and

a second handle provided at the proximal end of the assembly and being shaped for reception in the palm of a hand,

the assembly being capable of being inserted into tissue as a unit, and being such that the stylet can be withdrawn from the hollow needle while the latter remains inserted into the tissue to enable aspiration to be effected.

22. An aspiration needle assembly as claimed in claim 21, wherein the assembly is such that the stylet can be re-inserted into the hollow needle prior to withdrawal of the latter from the tissue.

23. An aspiration needle assembly as claimed in claim 21 or claim 22, wherein the hollow needle has an open distal end and wherein the stylet has a pointed distal end which projects through the open distal end of the hollow needle when the stylet is fully received within the hollow needle.

24. An aspiration needle assembly as claimed in claim 23, wherein the pointed end of the stylet is pyramidal.

25. An aspiration needle assembly as claimed in any one of claims 21 to 24, wherein the distal end of the hollow needle is externally bevelled and/or is provided with a plurality of external flutes.

26. An aspiration needle assembly as claimed in any one of claims 21 to 25, wherein the with means for attachment of a device for the application of a reduced pressure.

27. An aspiration needle assembly as claimed in claim 26, wherein the said means is so arranged that the said device can be attached at the open proximal end of the hollow needle when the stylet is absent.

28. An aspiration needle assembly as claimed in claim 26 or claim 27, wherein the said means is means for attachment of a syringe.

29. An aspiration needle assembly as claimed in any one of claims 21 to 28, wherein the number of the said perforations is from 7 to 20.

30. An aspiration needle assembly as claimed in any one of claims 21 to 28, wherein the number of the said perforations is from 7 to 15.

31. An aspiration needle assembly as claimed in any one of claims 21 to 28, wherein the number of the said perforations is from 10 to 15.

32. An aspiration needle assembly as claimed in any one of claims 21 to 31, wherein the said first handle is in the form of a transverse bar extending across and substantially at right angles to the said longitudinal axis.

33. An aspiration needle assembly as claimed in any one of claims 21 to 32, wherein the said first handle is provided at or in the region of the proximal end of the hollow needle and the said second handle is provided at the proximal end of the stylet.

34. An aspiration needle assembly as claimed in any one of claims 21 to 33, wherein the proximal end of the hollow needle and the proximal end of the stylet are provided with mutual engagement means to secure the stylet with the hollow needle.

35. An aspiration needle assembly as claimed in claims 33 and 34, wherein the part of the said mutual engagement means provided on the stylet is provided on the said second handle.

36. An aspiration needle assembly as claimed in claims 27 and 35, wherein the said means for attachment of a reduced-pressure-application device constitutes the part of the said mutual engagement means provided on the hollow needle.

37. An aspiration needle assembly as claimed in claims 35 and 36, wherein the said second handle provided at the proximal end of the stylet is provided with means for engagement with the said means for attachment of a reduced-pressure-application device.

38. An aspiration needle assembly as claimed in claim 37, wherein the said attachment means constitutes means for attachment of a syringe.

39. An aspiration needle assembly as claimed in any one of claims 21 to 38, wherein the hollow needle is of uniform internal circular cross-section throughout its length, optionally excepting its proximal end, and the stylet is of uniform external cross-section throughout its length (excluding any pointing at its distal end) such that the stylet fits snugly within the hollow needle.

40. An aspiration needle assembly as claimed

internal diameter within the range of from 1.5 to 4 mm.

41. An aspiration needle assembly as claimed in claim 39, wherein the hollow needle has an internal diameter within the range of from 1.5 to 3 mm.

42. An aspiration needle assembly as claimed in any one of claims 21 to 41, wherein the hollow needle is of uniform external cross-section throughout its length, except for any bevel and/or fluting at its distal end and optionally excepting its proximal end.

43. An aspiration needle assembly as claimed in claim 42, wherein the hollow needle has an external diameter within the range of from 2 to 5 mm.

44. An aspiration needle assembly as claimed in claim 42, wherein the hollow needle has an external diameter within the range of from 2 to 4 mm.

45. An aspiration needle assembly as claimed in any one of claims 21 to 44, wherein the said first handle contains one or more finger-receiving recesses in a side facing towards the said distal end.

46. An aspiration needle assembly as claimed in claim 45, wherein at least one of the said finger-receiving recesses is present on each side of the said longitudinal axis.

47. An aspiration needle assembly as claimed in any one of claims 21 to 46, wherein the said second handle is substantially dome-shaped.

48. An aspiration needle assembly as claimed in claim 47, wherein the said second handle is substantially hemispherical.

49. An aspiration needle as claimed in claim 1 substantially as described herein with reference to, and as shown in, Figs. 2 and 5 of the accompanying drawings.

50. An aspiration needle assembly as claimed in claim 21 substantially as described herein with reference to, and as shown in, Fig. 1 of the accompanying drawings.

51. An aspiration needle assembly as claimed in claim 21 substantially as described herein with reference to, and as shown in, Figs. 1 to 5 of the accompanying drawings.

52. An aspiration method, which comprises passing an aspiration needle provided with a plurality of perforations in a side wall of the needle into tissue to be aspirated, withdrawing an aspirate sample from the tissue into the needle through said perforations, retaining the sample, and removing the needle from the tissue.

53. An aspiration method, which comprises passing an aspiration needle as claimed in any one of claims 1 to 20 and 49 into tissue to be aspirated, withdrawing an aspirate sample from the tissue into the needle, and removing the needle from the tissue.

54. A method as claimed in claim 52 or claim 53, wherein the said tissue comprises bone marrow.

55. A method of aspirating bone marrow using an aspiration needle assembly as claimed in any one of claims 21 to 48, 50 and 51, which comprises passing the distal end of the assembly, with the stylet located within the hollow needle, through the soft tissue and bony cortex of a patient until the spongy bone is reached, advancing the assembly to the desired depth within the spongy bone, withdrawing the stylet from the hollow needle, applying a reduced pressure to the hollow needle to withdraw an aspirate sample from the bone marrow through the hollow needle, replacing the stylet within the hollow needle, and withdrawing the assembly from the patient.

56. A method as claimed in claim 55, carried out substantially as described herein.

57. An aspirate sample that has been obtained using an aspiration needle as claimed in any one of claims 1 to 20 and 49.

58. An aspirate sample that has been obtained using an aspiration needle assembly as claimed in any one of claims 21 to 48, 50 and 51.

59. An aspirate sample that has been obtained by a method as claimed in any one of claims 52 to 56.

60. An aspirate sample as claimed in any one of claims 57 to 59, which is a bone-marrow aspirate sample.

61. Any new feature or combination of features hereinbefore described.

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